

**OFFICIAL****BOX: ISSUE FEE**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**RECEIVED  
CENTRAL FAX CENTER**

DEC 16 2003

Appl. No. : 09/870,521  
Applicant : Marcia M. MILLER et al.  
Filed : June 1, 2001  
TC/A.U. : 1634  
Examiner : Ethan C. Whisenant

Docket No. : 1954-310  
Customer No. : 06449  
Confirmation No. : 1318

**Supplemental Information Disclosure Statement**

Director of the United States Patent  
and Trademark Office  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

Under the provisions of 37 C.F.R. §§1.56 and 1.98,  
Applicants submit herewith copies of publications that the Office  
may wish to consider in examination of the subject application.  
The publications are listed on the attached form PTO-1449.

Each item of information contained in this Information  
Disclosure Statement was cited in the enclosed International  
Search Report in connection with the International Application  
No. PCT/US01/17684. The International Search Report cites 8  
references, 5 of which are already of record in this application.

Reference A is a European Patent Application, which shares  
inventors with the present application and was cited as category  
"A," background information, in the International Search Report.  
It relates to Rfp-Y associated disease in domesticated fowl.

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Page 2

Reference B is a journal article dated by the Authority at March 1, 2001 and is cited category "XP." The article therefore is not prior art against this application, which enjoys a priority date of at least June 2, 2000.

Reference C is an abstract from the European Bioinformatics Institute which discloses a sequence also disclosed in reference B (see citation for reference B in Report). This abstract is dated March 9, 2001 and therefore also is not prior art against this application.

Reference D is an abstract, dated September 17, 1999, from the European Bioinformatics Institute. This reference is cited as category "X." The sequence disclosed in this abstract apparently is a segment of a cloned chicken T cell. This sequence contains within it, at bases 17-34 of the 558 base sequence, an unidentified portion which is homologous to SEQ ID NO:1 of the present application.

Respectfully submitted,

By 

Martha Cassidy  
Attorney for Applicants  
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1954-310.1ds3.wpd



<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				<i>Complete if Known</i>	
				Application Number	09/870,521
				Filing Date	June 1, 2001
				First Named Inventor	Marcia M. MILLER <i>et al.</i>
				Group Art Unit	1634
				Examiner Name	Ethan C. Whisenant
Sheet	2	of	2	Attorney Docket Number	1954-310
<b>NON PATENT LITERATURE DOCUMENTS</b>					
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published			T <sup>2</sup>
	B	Afanassieff, Marielle, <i>et al.</i> , "At Least One Class I Gene in Restriction Fragment Pattern-Y (Rfp-Y), the Second MHC Gene Cluster in the Chicken, Is Transcribed, Polymorphic, and Shows Divergent Specialization in Antigen Binding Region," <i>The Journal of Immunology</i> 166:3324-3333, 2001.			
	C	Database EMBL 'Online', Chicken MHC Rfp-Y Gene YFV-Y-FVW*7, Database Accession No. AF218784, XP002230335, March 9, 2001 (Abstract).			
	D	Database EMBL 'Online', Chicken mRNA Sequence, Database Accession No. AI980256, XP002230334, September 17, 1999 (Abstract) of Tirunagaru, Vijaya Gouri, <i>et al.</i> , "An Expressed Sequence Tag Database of T-Cell-Enriched Activated Chicken Splenocytes: Sequence Analysis of 5251 Clones," <i>Genomics</i> 66:144-151, 2000.			
Examiner Signature		Date Considered			

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code. <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language translation is attached. AB indicates that only an English language abstract is attached.

## PATENT COOPERATION TREATY

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

FIGG, E., Anthony  
Rothwell, Figg, Ernst & Manbeck, P.  
1425 K Street, N.W., Suite 800  
Washington, DC 20005  
ETATS-UNIS D'AMERIQUE

NOTIFICATION OF TRANSMITTAL OF  
INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT

(PCT Rule 71.1)

Date of mailing  
(day/month/year) 16/09/2003

Applicant's or agent's file reference  
1954-0310PCT

## IMPORTANT NOTIFICATION

International application No.

PCT/US 01/17684

International filing date (day/month/year)

01/06/2001

Priority date (day/month/year)

02/06/2000

Applicant

CITY OF HOPE

- The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
- A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
- Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

RECEIVED/FACILITIES  
ROTHWELL FIGG ERNST & MANBECK

FILE NO. 1954-0310PCT  
FAC PROC. INIT.

9-25-03

SEP 25 2003

## 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 33(2)). The applicant must also the reminder sent by the International Bureau with Form PCT/IB/301.

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the IPEA/



European Patent Office  
D-80298 Munich  
Tel. (+49-89) 2399-0, Tx: 523656 epmu d  
Fax: (+49-89) 2399-4465

Authorized officer

MORENO R A

Tel. (+49-89) 2399 2828



## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

(Rationalised Report according to the Notice of the President of the EPO published in the OJ11/2001)



Applicant's or agent's file reference <b>1954-0310PCT</b>	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. <b>PCT/US 01/ 17684</b>	International filing date (day/month/year) <b>01/06/2001</b>	Priority date (day/month/year) <b>02/06/2000</b>
International Patent Classification (IPC) or national classification and IPC <b>G12Q1/00</b>		
Applicant <b>CITY OF HOPE</b>		

- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 2 sheets, including this cover sheet.  
☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consists of a total of \_\_\_\_\_ sheets.

- This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand <b>24/12/2001</b>	Date of completion of this report <b>11/09/2003</b>
Name and mailing address of the IPEA/  European Patent Office D-80298 Munich Tel. (+49-89) 2399-0, Tx: 523656 epmu d Fax: (+49-89) 2399-4465	Authorized officer <b>LONATI M</b> Tel. (+49-89) 2399 2828 

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No PCT/US 01/17684

**I. Basis of the report**

The basis of this international preliminary examination is the application as originally filed.

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The question of whether the claimed invention appears to be novel, to involve an inventive step, or to be industrially applicable has not been the subject of the international preliminary examination in respect of the claims which have not been searched (Article 17(2)(a) or (3) and Rule 66.1(e) PCT); see also international search report).

**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability**

To the extent that the international preliminary examination has been carried out (see item III above), the following is pointed out:

In light of the documents cited in the international search report, it is considered that the invention as defined in at least some of the claims, which have been the subject of an international search report, does not appear to meet the criteria mentioned in Article 33(1) PCT, i.e. does not appear to be novel and/or to involve an inventive step (see international search report, in particular the documents cited X and/or Y and corresponding claim references).

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT  
OR THE DECLARATION

(PCT Rule 44.1)

To:  
FIGG, E., Anthony  
Attn: Figg, E., A.  
Rothwell, Figg, Ernst & Manbeck, P.  
1425 K Street, N.W.  
Washington, DC 20005  
UNITED STATES OF AMERICA

Date of mailing  
(day/month/year) 17/06/2003

Applicant's or agent's file reference  
1954-310.PCT

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No.  
PCT/US 01/17684

International filing date  
(day/month/year) 01/06/2001

Applicant

CITY OF HOPE

1. ☒ The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 48):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland  
Facsimile No.: (41-22) 740.14.95

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Further action(s): The applicant is reminded of the following:

Shortly after 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

Within 19 months from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within 30 months from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5018 Patentkanal 2  
NL-2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 851 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Heike Zoglauer

Form PCT/ISA/220 (July 1988)

\*\*\* FILE COPY \*\*\*



## PATENT COOPERATION TREATY

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>1954-310.PCT</b>	<b>FOR FURTHER ACTION</b> <small>see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.</small>	
International application No. <b>PCT/US 01/ 17684</b>	International filing date (day/month/year) <b>01/06/2001</b>	(Earliest) Priority Date (day/month/year) <b>02/06/2000</b>
Applicant <b>CITY OF HOPE</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 8 sheets.  
☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the International search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☒ furnished subsequently to this Authority in written form.

☒ furnished subsequently to this Authority in computer readable form.

☒ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☒ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

2. ☒ Certain claims were found unsearchable (See Box I).

3. ☒ Unity of invention is lacking (see Box II).

4. With regard to the title,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 23.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the drawings to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☒ None of the figures.

Form PCT/ISA/210 (first sheet) (July 1998)

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 01/17684**Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)**

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☒ Claims Nos.: 18-20  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:  
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

**Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)**

This International Searching Authority found multiple inventions in this International Application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:  
1,2,5,7,9,10 (in full); 13-17 (in part)

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

Form PCT/ISA/210 (continuation of first sheet (1)) (July 1998)

International Application No. PCT/US 01 17684

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1,2,5,7,9,10 (in full); 13-17 (in part)

A probe comprising at least 17 consecutive nucleotides from SEQ ID NO.1; a method for determining the Mhc genotype of a chicken using said probe; a probe having sequence defined by SEQ ID NO.1; a fragment of 17-625 nucleotides of the probe having SEQ ID NO.1; a probe which is at least 70% homologous to the probe having SEQ ID NO.1.

2. Claims: 3,4,6,8,11,12 (in full); 13-17 (in part)

A probe comprising at least 17 consecutive nucleotides from SEQ ID NO.2; a method for determining the Mhc genotype of a chicken using said probe; a probe having the sequence of SEQ ID NO.2; a fragment of 17-625 nucleotides of the probe having SEQ ID NO.2; a probe which is at least 70% homologous to the probe having SEQ ID NO.2.

International Application No. PCT/US 01 47684

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 18-20

Present claim 18 relates to a method defined by reference to a desirable characteristic or property, namely a correlation between an Mhc genotype and resistance to a preselected disease.

However, the present application provides no correlation between any genotype determined with the claimed probes and a disease. Therefore, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible.

Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the method by reference to a result to be achieved, namely the determined relationship between a genotype determined with a particular probe and the resistance of the chicken to a preselected disease. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible.

Therefore, no search has been carried out for the subject-matter of claim 18.

As claims 19 and 20 also refer back to claim 18, said claims have also not been searched.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

12.NOV.2003 15:32

EPO MUNICH 2 LCS +49 89 23991974

NR.301

S.6

## INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 01/17684

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C12Q1/68

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C12Q

Documentation searched other than minimum documentation in the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, EMBL, MEDLINE, BIOSIS, EMBASE, PAJ, WPI Data

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>DATABASE EMBL 'Online! Chicken mRNA sequence, 17 September 1999 (1999-09-17) retrieved from EMBL Database accession no. AI980256 XP002230334 abstract</p> <p style="text-align: center;">--- -/-</p>	1,2

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

## \* Special categories of cited documents:

- 'A' document defining the general state of the art which is not considered to be of particular relevance  
'E' earlier document but published on or after the international filing date  
'L' document which may throw doubt on priority claims or which is cited to establish the publication date of another citation or other special reason (as specified)  
'O' document referring to an oral disclosure, use, exhibition or other means  
'P' document published prior to the international filing date but later than the priority date claimed

- 'T' later document published after the international filing date or priority date and not in conflict with the application but cited to underlain the principle or theory underlying the invention  
'X' document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone  
'Y' document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art  
'Z' document member of the same patent family

Date of the actual completion of the international search

7 February 2003

Date of mailing of the international search report

17.08.03

Name and mailing address of the ISA

European Patent Office, P.O. Box 5618 Patentplatz 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 840-2040, Tx. 81 651 epo nl.  
Fax: (+31-70) 340-8018

Authorized officer

Bradbrook, D

Form PCT/ISA/210 (second sheet) (July 1992)

page 1 of 3

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/17684

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X,P	AFANASSIEFF M ET AL: "At least one class I gene in restriction fragment pattern-Y (Rfp-Y), the second MHC gene cluster in the chicken, is transcribed, polymorphic, and shows divergent specialization in antigen binding region." JOURNAL OF IMMUNOLOGY (BALTIMORE, MD.: 1950) UNITED STATES 1 MAR 2001, 'Online! vol. 166, no. 5, 1 March 2001 (2001-03-01), pages 3324-3333, XP002230333 ISSN: 0022-1767 the whole document -& DATABASE EMBL 'Online! Chicken MHC Rfp-Y gene YFV-Y-FVW*7, 9 March 2001 (2001-03-09) retrieved from EMBL Database accession no. AF218784 XP002230335 abstract	1,2,5,7, 9,10, 13-17
A	EP 0 866 135 A (HOPE CITY) 23 September 1998 (1998-09-23)  page 3, line 15 -page 4, line 31; example II	1,2,5,7, 9,10, 13-17
A	FR 2 771 422 A (CENTRE NAT RECH SCIENT) 28 May 1999 (1999-05-28) cited in the application page 2, paragraph 4 -page 8, paragraph 5; example 1	1,2,5,7, 9,10, 13-17
A	US 5 451 670 A (MILLER MARCIA M) 19 September 1995 (1995-09-19)  the whole document	1,2,5,7, 9,10, 13-17
A	MILLER M M ET AL: "TWO MHC CLASS I AND TWO MHC CLASS II GENES MAP TO THE CHICKEN RFP-Y SYSTEM OUTSIDE THE B COMPLEX" PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA, NATIONAL ACADEMY OF SCIENCE, WASHINGTON, US, vol. 91, no. 10, May 1994 (1994-05), pages 4397-4401, XP000877079 ISSN: 0027-8424 cited in the application abstract page 4398, column 1, paragraphs 2,3	1,2,5,7, 9,10, 13-17

-/-

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 01/17684

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	VALLEJO R L ET AL: "NON-ASSOCIATION BETWEEN RFP-Y MAJOR HISTOCOMPATIBILITY COMPLEX-LIKE GENES AND SUSCEPTIBILITY TO MAREK'S DISEASE VIRUS-INDUCED TUMOURS IN 63X72F2 INTERCROSS CHICKENS" ANIMAL GENETICS, BLACKWELL SCIENTIFIC PUBLICATIONS, LONDON, GB, vol. 28, 5 October 1997 (1997-10-05), pages 331-337, XP002074409 ISSN: 0268-9146 cited in the application abstract page 332, column 1, paragraph 4 -column 2, paragraph 1	1,2,5,7, 9,10, 13-17
A	JUUL-MADSEN H R ET AL: "NEW CHICKEN RFP-Y HAPLOTYPES ON THE BASIS OF MHC CLASS II RFLP AND MLC ANALYSES" IMMUNOGENETICS, SPRINGER VERLAG, BERLIN, DE, vol. 45, no. 6, 1997, pages 345-352, XP000892281 ISSN: 0093-7711 cited in the application abstract page 346, column 1, paragraph 4	1,2,5,7, 9,10, 13-17

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 01/17684

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0866135	A	23-09-1998	US 5944652 A	31-08-1999
			AU 4924697 A	02-07-1998
			CA 2225990 A1	27-06-1998
			EP 0866135 A2	23-09-1998
			JP 10248434 A	22-09-1998
			US 6242182 B1	05-06-2001
FR 2771422	A	28-05-1999	FR 2771422 A1	28-05-1999
			EP 1032702 A1	06-09-2000
			WO 9927132 A1	03-06-1999
US 5451670	A	19-09-1995	US 6216106 B1	17-04-2001
			CA 1340388 A1	09-02-1999

Form PCT/ISA/210 (patent family annex) (July 1999)



## PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:  
 FIGG, E., Anthony ψ  
 Attn. Figg, E., A.  
 Rothwell, Figg, Ernst & Manbeck, P.  
 1425 K Street, N.W.  
 Washington, DC 20005  
 UNITED STATES OF AMERICA

## INVITATION TO PAY ADDITIONAL FEES

(PCT Article 17(3)(a) and Rule 40.1)

REGISTERED MAIL

Date of mailing (day/month/year)	06/03/2003
Applicant's or agent's file reference 1954-310.PCT	PAYMENT DUE within 45 <del>1000</del> days from the above date of mailing
International application No. PCT/US 01/17684	International filing date (day/month/year) 01/06/2001
Applicant CITY OF HOPE	

## 1. This International Searching Authority

- (i) considers that there are 2 (number of) inventions claimed in the international application covered by the claims indicated ~~on~~ on the extra sheet:

and it considers that the international application does not comply with the requirements of unity of invention (Rules 13.1, 13.2 and 13.3) for the reasons indicated ~~on~~ on the extra sheet:

MAR 13 2003

EAP/PL/288  
1954-310.PCT

- (ii) ☒ has carried out a partial international search (see Annex) ☐ will establish the international search report on those parts of the international application which relate to the invention first mentioned in claims Nos.:  
 1,2,5,7,9,10 (in full); 13-17 (in part)
- (iii) will establish the international search report on the other parts of the international application only if, and to the extent to which, additional fees are paid

## 2. The applicant is hereby invited, within the time limit indicated above, to pay the amount indicated below:

EUR 945,00 x 1 = EUR 945,00  
 Fee per additional invention number of additional inventions total amount of additional fees

Or, \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_

The applicant is informed that, according to Rule 40.2(c), the payment of any additional fee may be made under protest, i.e., a reasoned statement to the effect that the international application complies with the requirement of unity of invention or that the amount of the required additional fee is excessive.

3. ☒ Claim(s) Nos. 18-20 have been found to be unsearchable under Article 17(2)(b) because of defects under Article 17(2)(a) and therefore have not been included with any invention.

Name and mailing address of the International Searching Authority

European Patent Office, P.B. 5518 Patentlaan 2  
 NL-2280 HV Rijswijk  
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,

Authorized officer

Heike Zoglauer

## INVITATION TO PAY ADDITIONAL FEES

International application No.

PCT/US 01/17684

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1,2,5,7,9,10 (in full); 13-17 (in part)

A probe comprising at least 17 consecutive nucleotides from SEQ ID NO.1; a method for determining the Mhc genotype of a chicken using said probe; a probe having sequence defined by SEQ ID NO.1; a fragment of 17-625 nucleotides of the probe having SEQ ID NO.1; a probe which is at least 70% homologous to the probe having SEQ ID NO.1.

2. Claims: 3,4,6,8,11,12 (in full); 13-17 (in part)

A probe comprising at least 17 consecutive nucleotides from SEQ ID NO.2; a method for determining the Mhc genotype of a chicken using said probe; a probe having the sequence of SEQ ID NO.2; a fragment of 17-625 nucleotides of the probe having SEQ ID NO.2; a probe which is at least 70% homologous to the probe having SEQ ID NO.2.

The above inventions share the following common concept: both relate to oligonucleotides which hybridize to the Mhc region in chickens, and their use in genotyping chickens.

This concept cannot be considered as a single inventive concept in the sense of Rule 13.2 PCT for the following reasons:

Oligonucleotide probes for genotyping the chicken Mhc region are well established in the art (e.g. Miller et al., 1994; US5451670; Vallejo et al., 1997; Juul-Madsen et al., 1997). Moreover, nucleic acid molecules which are designed to be specific for either the Rfp-Y or the B loci are also known from the prior art (cf EP0866135; FR2771422).

Therefore, in the light of the prior art, the problem to be solved by the present application is the provision of further nucleic acid molecules which hybridize specifically with distinct portions of the Mhc region in chickens, and their use in genotyping. Each of SEQ ID NOs 1 and 2 is considered to be a separate solution to this problem: SEQ ID NO:1 hybridizes to the Rfp-Y locus, and SEQ ID NO:2 hybridizes to the B locus.

Due to the fact that said nucleic acid molecules do not share any common structural element and no other feature could be identified which might be considered to represent the special technical feature in the sense of Rule 13.2 PCT, the present application does not meet the requirements of Rule 13.1 PCT with respect to unity of invention, and is considered to consist of the two separate inventions listed above.

The ISA has searched the first invention, relating to SEQ ID NO.1.

International Application No. PCT/US 01 47684

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 206

Continuation of Box 3.

Claims Nos.: 18-20

Present claim 18 relates to a method defined by reference to a desirable characteristic or property, namely a correlation between an Mhc genotype and resistance to a preselected disease.

However, the present application provides no correlation between any genotype determined with the claimed probes and a disease. Therefore, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible.

Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the method by reference to a result to be achieved, namely the determined relationship between a genotype determined with a particular probe and the resistance of the chicken to a preselected disease. Again, this lack of clarity in the present case is such as to render a meaningful search over the whole of the claimed scope impossible.

Therefore, no search has been carried out for the subject-matter of claim 18.

As claims 19 and 20 also refer back to claim 18, said claims have also not been searched.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

Annex to Form PCT/ISA/206  
**COMMUNICATION RELATING TO THE RESULTS  
 OF THE PARTIAL INTERNATIONAL SEARCH**

International Application No  
**PCT/US 01/17684**

1. The present communication is an Annex to the invitation to pay additional fees (Form PCT/ISA/206). It shows the results of the international search established on the parts of the international application which relate to the invention first mentioned in claims Nos.:
- see 'Invitation to pay additional fees'
2. This communication is not the international search report which will be established according to Article 18 and Rule 43.
3. If the applicant does not pay any additional search fees, the information appearing in this communication will be considered as the result of the international search and will be included as such in the international search report.
4. If the applicant pays additional fees, the international search report will contain both the information appearing in this communication and the results of the international search on other parts of the international application for which such fees will have been paid.

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DATABASE EMBL 'Online! Chicken mRNA sequence, 17 September 1999 (1999-09-17) retrieved from EMBL Database accession no. AI980256 XP002230334 abstract	1,2
X,P	AFANASSIEFF M ET AL: "At least one class I gene in restriction fragment pattern-Y (Rfp-Y), the second MHC gene cluster in the chicken, is transcribed, polymorphic, and shows divergent specialization in antigen binding region." JOURNAL OF IMMUNOLOGY (BALTIMORE, MD.: 1950) UNITED STATES 1 MAR 2001, 'Online! vol. 166, no. 5, 1 March 2001 (2001-03-01), pages 3324-3333, XP002230333 ISSN: 0022-1767 the whole document -& DATABASE EMBL 'Online! Chicken MHC Rfp-Y gene YFV-Y-FVw*7, 9 March 2001 (2001-03-09) retrieved from EMBL Database accession no. AF218784 XP002230335 abstract	1,2,5,7, 9,10, 13-17



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

\* Special categories of cited documents:

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

Annex to Form PCT/ISA/206  
**COMMUNICATION RELATING TO THE RESULTS  
 OF THE PARTIAL INTERNATIONAL SEARCH**

International Application No

PCT/US 01/17684

**C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 866 135 A (HOPE CITY) 23 September 1998 (1998-09-23)  page 3, line 15 -page 4, line 31; example II	1,2,5,7, 9,10, 13-17
A	FR 2 771 422 A (CENTRE NAT RECH SCIENT) 28 May 1999 (1999-05-28) cited in the application page 2, paragraph 4 -page 8, paragraph 5; example 1	1,2,5,7, 9,10, 13-17
A	US 5 451 670 A (MILLER MARCIA M) 19 September 1995 (1995-09-19)  the whole document	1,2,5,7, 9,10, 13-17
A	MILLER M M ET AL: "TWO MHC CLASS I AND TWO MHC CLASS II GENES MAP TO THE CHICKEN RFP-Y SYSTEM OUTSIDE THE B COMPLEX" PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA, NATIONAL ACADEMY OF SCIENCE, WASHINGTON, US, vol. 91, no. 10, May 1994 (1994-05), pages 4397-4401, XP000877079 ISSN: 0027-8424 cited in the application abstract page 4398, column 1, paragraphs 2,3	1,2,5,7, 9,10, 13-17
A	VALLEJO R L ET AL: "NON-ASSOCIATION BETWEEN RFP-Y MAJOR HISTOCOMPATIBILITY COMPLEX-LIKE GENES AND SUSCEPTIBILITY TO MAREK'S DISEASE VIRUS-INDUCED TUMOURS IN 63X72F2 INTERCROSS CHICKENS" ANIMAL GENETICS, BLACKWELL SCIENTIFIC PUBLICATIONS, LONDON, GB, vol. 28, 5 October 1997 (1997-10-05), pages 331-337, XP002074409 ISSN: 0268-9146 cited in the application abstract page 332, column 1, paragraph 4 -column 2, paragraph 1	1,2,5,7, 9,10, 13-17

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Annex to Form PCT/ISA/206  
COMMUNICATION RELATING TO THE RESULTS  
OF THE PARTIAL INTERNATIONAL SEARCH

International Application No

PCT/US 01/17684

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	JUUL-MADSEN H R ET AL: "NEW CHICKEN RFP-Y HAPLOTYPES ON THE BASIS OF MHC CLASS II RFLP AND MLC ANALYSES" IMMUNOGENETICS, SPRINGER VERLAG, BERLIN, DE, vol. 45, no. 6, 1997, pages 345-352, XP000892281 ISSN: 0093-7711 cited in the application abstract page 346, column 1, paragraph 4	1,2,5,7, 9,10, 13-17

## Patent Family Annex

Information on patent family members

International Application No

PCT/US 01/17684

Patent document cited in search report		Publication date	Patent family member(s)	Publication date	
EP 0866135	A	23-09-1998	US	5944652 A	31-08-1999
			AU	4924697 A	02-07-1998
			CA	2225990 A1	27-06-1998
			EP	0866135 A2	23-09-1998
			JP	10248434 A	22-09-1998
			US	6242182 B1	05-06-2001
FR 2771422	A	28-05-1999	FR	2771422 A1	28-05-1999
			EP	1032702 A1	06-09-2000
			WO	9927132 A1	03-06-1999
US 5451670	A	19-09-1995	US	6218106 B1	17-04-2001
			CA	1340388 A1	09-02-1999